K050208

JUN 14 2005

510(k) SUMMARY

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: June 6, 2005

TRADE OR PROPRIETARY NAME: FRIADENT® EsthetiCap

CLASSIFICATION NAME: Endosseous dental implant abutment (872.3630)

PREDICATE DEVICES: FRIADENT® ProTect Abutment cleared under 510(k) premarket notification K974628 on March 11, 1998 and K013867 on March 15, 2002 as well as to the Nobel Biocare Temp Abut Plastic Engaging Select NP cleared under 510(k) premarket notification K023113 on September 26, 2002

DEVICE DESCRIPTION:

The FRIADENT® EsthetiCap abutments create anatomic, esthetic peri-implant gingival contours by simple customization. FRIADENT® EsthetiCap abutments are available in five diameters (3.4 mm – 6.5 mm) and two shapes (oval and triangular) that reproduce the cross-section of the tooth at the cementum-enamel junction (CEJ).

INTENDED USE:

The FRIADENT® EsthetiCap is an anatomically shaped abutment used for fabrication of screw-retained or cementable temporary crowns or bridges The FRIADENT® EsthetiCap is a short-term provisional abutment for esthetic shaping of soft tissue.

TECHNOLOGICAL CHARACTERISTICS:

The FRIADENT® EsthetiCap and the predicate devices are similar in design and technological characteristics. The FRIADENT® EsthetiCap and the predicate devices are made of plastic materials. Both the FRIADENT® EsthetiCap and the predicate device FRIADENT® ProTect are available in the corresponding implant diameters and use similar laboratory components. The predicate device, Nobel Biocare Temp Abut Plastic Engaging Select NP is available in only one diameter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Helen Lewis
DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K050208
Trade/Device Name: FRIADENT® EsthetiCap
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 18, 2005
Received: May 19, 2005

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jeanette Y. Michaels M.D.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K050208

Device Name: **FRIADENT® EsthetiCap**

Indications for Use:

FRIADENT® EsthetiCap is an anatomically shaped abutment used for fabrication of screw-retained or cementable temporary crowns or bridges. The FRIADENT® EsthetiCap is a short-term provisional abutment for esthetic shaping of soft tissue.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeanette Y. Michaels M.D.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050208